

REMARKS/ARGUMENTS

Claims 1-55 remain pending in this application for consideration.

Claims 1, 21, and 45 have been amended to change "the method comprising" to "the method comprising the steps of" in order to overcome the Examiner's informality objection.

The paragraph at page 7, line 9 of the specification has been amended as indicated in order to overcome the Examiner's informality objection.

The Examiner objected to misnumbered claims 21-54, and stated that they had been renumbered them as 22-55. Applicant notes that the incorrect claim numbering was discussed in a telephone conversation with the Examiner, and that Applicant filed a Preliminary Amendment on February 8, 2002 correcting the misnumbered claims.

Rejection Under 35 U.S.C. § 112

The Examiner rejected claim 44 under 35 U.S.C. §112 on the basis that the recited laboratory information system, which is coupled to individual laboratory instruments and in communication with the normalization server, is not described or defined. Applicant directs the Examiner to page 5, lines 16-17, where the laboratory information system (LIS) is described as being in direct communication with one or more laboratory instruments. This is further illustrated in Fig. 1, where the laboratory information system (LIS) 18 is shown connected to several laboratory instruments 20 in order to facilitate such communication. Further, page 7, lines 4-6 of the specification describes how the laboratory information system (LIS) "communicates with the normalization server and sends the output data from each laboratory instrument in a manner which is formatted to facilitate normalization." Page 7, lines 11-12 of the specification further describes how the laboratory information system (LIS) may format the data

in a manner to facilitate its processing. Thus, the laboratory information system (LIS) is sufficiently described and defined in the application as submitted, and the Examiner's rejection should be withdrawn. Claim 44 should thus be allowed.

Rejections Under 35 U.S.C. § 102(b)

The Examiner rejected claims 1-14, 16, 19 and 41-43 as anticipated by U.S. Patent No. 5,646,046 to Fischer et al. ("Fischer"). Fischer discloses an automated spectrophotometric analyzer and method for testing blood samples for thrombosis and hemostasis properties in a clinical laboratory. The Fischer invention is directed to collecting, processing, reporting, and verifying data (col. 3, lines 52-63) from an individual automated analyzer (col. 4, lines 60-65). Fischer discloses an automated analyzer (col. 5, lines 60-64) with the capability of monitoring the performance and validity of the reported data on the analyzer (col. 3, lines 60-63). Contrary to the Examiner's statement, Fischer does not teach or suggest obtaining data from a group of instruments and then normalizing the data according to a control group.

Claim 1

Claim 1 (as amended) of the present application requires a method comprising the steps of: (1) "obtaining data indicative of testing specimen outputs of the group of laboratory instruments" and (2) "normalizing the data according to a control group". While an individual analyzer of Fischer does employ a normalization routine (col. 21, lines 33-44), the normalization occurs on data collected on that particular analyzer (col. 22, lines 44-67 through col. 23, lines 1-4), not on data from a group of laboratory instruments as required by all of the claims of the present application.

The portion of the specification cited by the Examiner (col. 26, lines 56-67; col. 27, lines 1-11) as indicating a method of modifying data from a group of laboratory instruments in fact discusses an individual analyzer's ability to normalize that particular analyzer's mechanical variables. The term "analyzer" or "instrument" as used in Fischer is comparable to "laboratory instrument" as used in the present application. The cited portion of Fischer, "... (t)he analyzer's calibration procedure normalized instrument mechanical variables ..." clearly points out that the instrument of Fischer normalizes variations present on that particular analyzer. Thus the analyzer in Fischer itself normalizes data that it collects itself, there is no compilation of data from multiple analyzers as required in all of the claims of the present application.

The Examiner further cites Fischer column 20, lines 20-26, as disclosing "obtaining data indicative of a group of laboratory instruments", and column 20, line 61 through column 22, line 42 as disclosing "normalizing that group of data according to a control group." As discussed above, Fischer discloses that an individual analyzer can collect and normalize data, and the cited portion of Fischer describes various normalization methods for the individual instruments in great detail. There is, however, no disclosure in Fischer that data from more than one analyzer be collected and that the group data be normalized, as required in all of the claims of the present application. In fact, Fischer teaches that the normalization be done at the analyzer as part of the analyzer's calibration procedure (col. 27, lines 1-5), and thus teaches away from the method claimed in the present application, where data is collected from multiple laboratory instruments and normalized according to a control group.

Thus, because Fischer does not disclose a method for modifying data from a group of laboratory instruments comprising the steps of: (1) obtaining data indicative of testing specimen outputs of the group of laboratory instruments and (2) normalizing the data according

to a control group, the claims of the present application are not anticipated by Fischer, and should be allowed.

Claims 2-14, 16, and 19

Claims 2-14, 16, and 19 depend from claim 1, discussed above. Since claim 1 is allowable for the reasons discussed above, these claims are thus also allowable.

Claims 41-43

Claims 41-43 describe the components and structure of a system to perform the method of claim 1, including one or more groups of laboratory instruments. As discussed above with respect to claim 1, Fischer discloses an individual analyzer capable of collecting and normalizing data. There is, however, no disclosure in Fischer that data from more than one analyzer be collected and that the group data be normalized, as required in claims 41-43 of the present application. Thus, claims 41-43 are not anticipated by Fischer, and should be allowed.

Rejections Under 35 C.F.R. § 103(a)

The Examiner rejected claims 20, 21-36, 39-40 , 45-54, and 55 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,646,046 to Fischer et al. ("Fischer"), discussed above.

Claims 20 and 55

With respect to claims 20 and 55, the Examiner specifically argues that Fischer teaches a method for modifying data from a group of laboratory instruments comprising the steps of: (1) obtaining data from the group of laboratory instruments and (2) normalizing the data according to a control group, and that it would have been obvious to use a computer system as in claims 20 and 55 of the present application to perform those steps.

As discussed above with respect to claim 1, Fischer discloses an analyzer which itself collects data and normalizes the collected data. There is absolutely no disclosure, teaching or suggestion in Fischer to obtain data from multiple analyzers and to perform normalization on that collected group of data, as required in all of the claims of the present application. In fact, by teaching that the normalization function be performed by the individual analyzer as part of the analyzer's calibration routine (col. 27, lines 1-4), Fischer, in fact, teaches away from the method claimed in the present application where data from multiple instruments is compiled and normalized. Thus, claims 20 and 55 of the present application are not obvious in view of Fischer, and should be allowed.

Claims 21-36 and 39-40

With respect to independent claim 21, and its dependent claims 22-36 and 39-40, the Examiner argues that Fischer teaches a method for modifying data from a group of laboratory instruments comprising the steps of: (1) obtaining data from the group of laboratory instruments and (2) normalizing the data according to a control group, and that it would have been obvious to modify data from more than one group of laboratory instruments as claimed in the present application.

Fischer discloses an analyzer which itself collects data and performs normalization of the collected data. There is absolutely no disclosure, teaching or suggestion in Fischer to obtain data from more than one analyzer and to perform normalization on that group data, as required in the claims of the present invention. In fact, by teaching that the normalization function be performed by the analyzer as part of the analyzer's calibration routine (col. 27, lines 1-4), Fischer, in fact, teaches away from the method claimed in the present

application where data from multiple instruments is compiled and normalized. Since there is no teaching, suggestion, or disclosure in Fischer to obtain data from a group of laboratory instruments, there is certainly no teaching, suggestion, or disclosure to obtain data from separate groups of laboratory instruments. Claims 21-36 and 39-40 are thus patentable over Fischer, and should be allowed.

Claims 45-54

With respect to independent claim 45, and dependent claims 46-54, the Examiner argues that Fischer teaches a method for modifying data from a group of laboratory instruments comprising the steps of: (1) obtaining data from the group of laboratory instruments and (2) normalizing the data according to a control group, and that it would have been obvious to one skilled in the art to standardize the results from a plurality of laboratory instruments.

As discussed above, Fischer discloses an analyzer which itself collects data and normalizes the collected data. There is absolutely no disclosure, teaching or suggestion in Fischer to obtain data from more than one analyzer and to perform normalization on that group of data, as required in the claims of the present application. In fact, by teaching that the normalization function be performed by the analyzer as part of the analyzer's calibration routine (col. 27, lines 1-4), Fischer, in fact, teaches away from the method claimed in the present application where group data from multiple instruments is collected and normalized. Claims 45-54 are thus patentable over Fischer, and should be allowed.

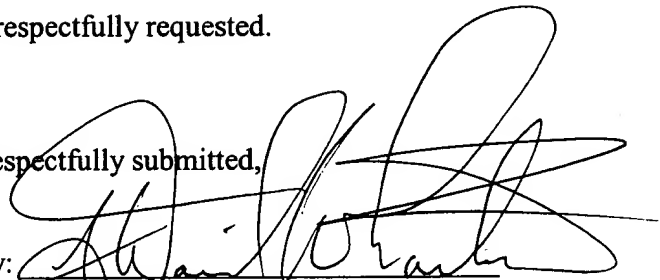
In view of the foregoing amendments and remarks, it is respectfully submitted that the claims are now in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments which

need be addressed in order to obtain allowance, he is invited to contact the undersigned attorney at the number listed below.

Acknowledgement of receipt is respectfully requested.

Respectfully submitted,

By:

A large, stylized handwritten signature in black ink, likely belonging to J. David Wharton, is written over the signature line and extends into the contact information area.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

The paragraph beginning at page 7, line 9 has been amended as follows:

In a second embodiment, a direct communications link, such as a telephone modem connection, is established by the LIS or the normalization server for the purpose of transferring the output data. Additionally, prior to sending the laboratory instrument output data to the normalization server, the LIS may format the data in a manner to facilitate its processing. alternatively, a graphical interface may be established between the LIS and the normalization server, such as an input screen, to allow the manual entry of the output data over the communications link to the normalization server. In a third embodiment, the output from the laboratory instrument group may be physically sent to the normalization server provider and entered manually via a plurality of data input methods. As would be understood, alternative data transfer embodiments or a combination of the above mentioned embodiments are within the scope of the present invention.

In the Claims:

Claim 1 has been amended as follows:

1. (Amended) A method for modifying data from a group of laboratory instruments, the method comprising the steps of:
 - obtaining data indicative of testing specimen outputs of the group of laboratory instruments; and
 - normalizing the data according to a control group.

Claim 21 has been amended as follows:

21. (Amended) A method for modifying data from two or more groups of laboratory instruments, the method comprising the steps of:

obtaining testing specimen outputs from a first of the two or more groups of laboratory instruments;

obtaining testing specimen outputs from a second of the two or more groups of laboratory instruments; and

normalizing the testing specimen outputs from the first and second groups of laboratory instruments.

Claim 45 has been amended as follows:

45. (Amended) A method for standardizing instrument results from a plurality of laboratory instruments, the method comprising the steps of:

obtaining testing specimen data from a first of a group of laboratory instruments;

normalizing the first laboratory instrument testing specimen data according to a first normalization curve; and

adjusting the first laboratory instrument data according to the first normalization curve.